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K034048

510(k) Summary
R&D Systems, Inc. GLU-LINE Hematology Control

Date of Summary:	December 16, 2003
Company Name:	R&D Systems, Inc. 614 McKinley Place N.E. Minneapolis, MN 55413
Contact name:	Ralph E. Hogancamp 612-656-4413, FAX 612-379-6809
Classification name:	Hematology Quality Control Mixture
Product name:	R&D GLU-LINE Hematology Control
CFR section:	864.8625 Hematology quality control mixture.
Device Class:	Class II

Predicate Device: R&D Systems Glucose Hemoglobin Hematology Control, K993321 manufactured by R&D Systems, Inc. 614 McKinley Place N.E., Minneapolis, MN 55413

Description: This control is a multilevel control that provides a means of measuring the linearity of glucose analyzers for the glucose parameter.

Intended use: R&D GLU-LINE Hematology Control is designed as a multilevel control that provides a means of measuring the linearity of glucose analyzers for the glucose parameter.

Comparison: Both products are used to monitor glucose on hematology instruments.

Discussion: Laboratory testing of 3 validation lots has shown R&D GLU-LINE Hematology Control to have substantial equavalence in performance, precision and stability to the predicate device. R&D GLU-LINE Hematology Control passed the acceptance criteria of remaining within the assay range over the life of the product. R&D GLU-LINE Hematology Control has demonstrated precision as indicated by the small standard deviation obtained during laboratory testing. Expiriation dating has been established at 105 days (closed vial) when stored at 2 - 8° C and handled according to instructons for use.

Conclusion: R&D GLU-LINE Hematology Control is a safe and effective control for the above intended use when used as instructed in the package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 0 2004

Mr. Ralph E. Hogancamp
Quality Assurance Specialist
R & D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413

Re: k034048
Trade/Device Name: R & D GLU-LINE Hematology Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material(assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: December 24, 2003
Received: December 30, 2003

Dear Mr. Hogancamp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Device Name: R&D GLU-LINE Hematology Control

Indications for Use:

R&D GLU-LINE Hematology Control is a multilevel control that provides a means of measuring the linearity of glucose analyzers for glucose parameter determinations.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse _____

(Optional Format 1-2-96)

Carol Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K034048